DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–0352]

Status of Useful Written Prescription Drug Information for Patients; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to discuss the findings of the interim study of the status of useful written prescription drug information for patients consistent with the criteria specified in the ''Action Plan for the Provision of Useful Prescription Medicine Information'' (Action Plan). The purpose of this meeting is to present the study methodology and results and seek feedback prior to developing assessment of the year 2000 goals. The meeting will begin with presentations about the report and findings, followed by small group discussions and feedback. FDA encourages interested individuals to attend this meeting or submit comments.

DATES: The public meeting will be held on Tuesday, February 29, 2000, from 1 p.m. to 5:30 p.m. and Wednesday, March 1, 2000, from 8:30 a.m. to 3 p.m. The deadline for registration is February 18, 2000. Early registration is recommended, as space is limited. Registration and dissemination of materials will begin at 11 a.m. on February 29, 2000. Written comments will be accepted until April 28, 2000.

ADDRESSES: The public meeting will be held at the DoubleTree Hotel, 1750 Rockville Pike, Rockville MD 20852. Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville MD 20852. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document.

NM1

A copy of the study report, as well as registration information, can be obtained at http://www.fda.gov/cder/calendar/meeting/rx2000. A transcript and summary of the meeting may be seen at the Dockets Management Branch (address above).

FOR FURTHER INFORMATION CONTACT: Marcia L. Trenter, Center for Drug Evaluation and Research (HFD–210), Food and Drug Administration, 5600 Fisher Lane, Rockville, MD 20857, 301–827–1674, or e-mail: trenterm@cder.fda.gov).

SUPPLEMENTARY INFORMATION: Inadequate access to useful patient information is a major cause of inappropriate use of prescription medicines, leading to serious personal injury and costs to the health care system. While the rate of distribution of written prescription drug information materials has increased somewhat over the past 15 years, the quality of such material has been quite variable.

In the **Federal Register** of August 24, 1995 (60 FR 44182), FDA published a proposed rule that aimed to increase the quality and quantity of written information about prescription medicines given to patients. In the proposed rule, entitled ''Prescription Drug Product Labeling; Medication Guide Requirements,'' FDA encouraged the private sector to develop and distribute patient-oriented written information leaflets for all prescription drugs, and set targets for the distribution of these leaflets. In addition to setting target distribution goals by specific dates, the proposed rule set criteria by which written information would be judged to determine whether it was ''useful'' and should therefore count toward accomplishment of the target goals.

In August 1996, the U.S. Congress passed Public Law 104–180 mandating that the private sector be given the opportunity to meet distribution and quality goals for written patient prescription medicine information. It also directed that the Secretary of Health and Human Services (the Secretary) facilitate the development of a long-range comprehensive action plan to meet these goals through private-sector efforts.

The Secretary asked the Keystone Center to convene a Steering Committee to collaboratively develop this action plan. The Action Plan accepted by the Secretary in January 1997 reiterated the target goals specified in the Federal legislation. These goals were that by the year 2000 useful

written information would be distributed to 75 percent of individuals receiving new prescriptions for medicines, and by the year 2006 to 95 percent of such individuals. The Action Plan generally endorsed the conceptual criteria specified in Public Law 104–180 for defining the usefulness of medication information. Specifically, it stated that such materials should be: (1) Scientifically accurate; (2) unbiased in content and tone; (3) sufficiently specific and comprehensive; (3) presented in an understandable and legible format that is readily comprehensible to consumers; (4) timely and up to date; and (5) useful, that is, enables the consumer to use the medicine properly and appropriately, receive the maximum benefit, and avoid harm. The Action Plan, including descriptions of the criteria, is available on the Internet at http://www.nyam.org/library/keystone.

Consistent with Public Law 104–180, the Action Plan called for the development of a mechanism to periodically assess the quality of written prescription information for patients. To test a methodology for collecting patient information materials and assessing their usefulness, FDA developed a contract with the National Association of Boards of Pharmacy. The contract called for the selection of several State Boards of Pharmacy who would arrange for collecting, from a sample of State pharmacies, medication information materials given with new prescriptions for three commonly prescribed prescription drugs. The contract also called for the development of evaluation materials to assess the usefulness of the information through application of the Action Plan criteria. The medication information materials were collected in 1999, and the final report from the evaluation was completed in December 1999. The report is available on the Internet at http://www.fda.gov/cder/calendar/meeting/rx2000.

FDA is seeking comments on several issues:

- What should be the minimum standard or threshold that must be met for written information to be considered useful?

- Should certain criteria derived from the Action Plan recommendations be given more weight than others? If so, which criteria should be weighted more strongly, and why?

- Are the evaluation forms an accurate translation of the Action Plan's criteria?